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3. 510(K) SUMMARY

1. Applicant/Sponsor: Valpo Orthopedic Technology, Inc.
438 E 200 N
Warsaw, IN 46582

FEB 9

2. Contact Person: Hans Stover
President & CEO
hstover@votechnology.com
Phone (574) 269-4103, Ext 222

3. Proprietary Name: Unicompartmental Knee

4. Common Name: Unicondylar Knee

5. Classification Name: Knee joint, femorotibial metal/polymer semi-constrained cemented Prosthesis (21 CFR 888.3530)

6. Legally Marketed Devices to which Substantial Equivalence is Claimed:

a. Repicci II Unicompartmental Knee. (K971938)

b. Zimmer Unicompartmental Knee System (K033363)

c. Miller /Galante Precoat Unicompartmental Knee (K010685)

d. EIUS Unicompartmental Knee System –(K033769)

e. Active Unicompartmental Knee System—(K060412)

f. Repicci II Unicondylar Knee System—(K020264)

7. Device Description:
The VOT Uni Knee consists of a femoral and a tibial component. The low profiled prosthesis is designed to be nonconstraining and to allow natural weight distribution and

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flexion. The anatomically designed femoral component is asymmetrically shaped conforming to the natural knee in the coronal and sagittal planes. The post and keel are designed to provide anteroposterior and mediolateral stability. Cobalt Chrome Alloy is used to fabricate the component which is available in three sizes. The tibial component is manufactured from Ultra-High Molecular Weight Polyethylene (UHMWPe). It incorporates a hemispherical shaped articular surface to replicate the natural knee. The component is nonconstraining and designed to allow natural weight distribution and flexion. Dovetailed channels on the undersurface allow for mechanical lock between the implant and the cement mantle. The thickness of the component under the area of the femoral-tibial articulation helps to improve longevity and to minimize the possibility of its fracture. The dual injection ports, the cement delivery instruments, syringe and adapter facilitate cement application. Nine sizes are available to enhance surgical latitude in preoperative planning. Tibial and femoral instruments and trials are also available to facilitate implantation.

The VOT Unicompartmental Knee is solely indicated for medial compartment replacement of the articulating surface of the knee when only one side of the joint is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty procedures. The device is intended for cement use only.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 2008

Valpo Orthopedic Technology, Inc.
% Mr. Hans Stover
President & CEO
438 E 200 N
Warsaw, Indiana 46582

Re: K072704
Trade/Device Name: Unicompartmental Knee
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint, femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HRY
Dated: January 24, 2008
Received: January 25, 2008

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): ~~N/A (unknown)~~ K072704

Device Name: Unicompartmental Knee

Indications for Use:

The Unicompartmental Knee is indicated for:

The Unicompartmental Knee is solely indicated for medial compartment replacement of the articulating surface of the knee when only one side of the joint is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty procedures. This device is intended for cemented use only.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K072704